REMARKS

Reconsideration of the above-identified application as amended is requested. Claims 1-4 and 15 remain in this application. Claim 1 has been amended, support for this amendment can be found throughout the specification.

Rejection of claims 1-4 and 15 under 35 U.S.C. §103(a)

Claims 1-4 and 15 have been rejected under 35 U.S.C. §103(a) over Royce in view of Folkers et al., the Examiner taking the position that "it would have been obvious to one ordinary skilled to deliver fluvastatin in the vehicle of Royce to achieve the beneficial effect of an HMG-CoA reductase inhibitor in view of Folkers et al." Applicants respectfully traverse this rejection.

Folkers et al. relates to "methods and compositions for reducing side effects of HMG-CoA reductase inhibitor therapy particularly those related to the physiologically depressed levels of coenzyme Q10 in the animal".

This reference has been cited by the Examiner to demonstrate that fluvastatin is well known in the art as an HMG-CoA reductase inhibitor.

We agree that fluvastatin is known in the art.

Folkers et al. teaches that use of fluvastatin in compositions "for reducing side effects of HMG-CoA reductase inhibitor therapy particularly those related to the physiologically depressed levels of coenzyme Q10 in the animal".

There is no relation between this cited document and the fluvastatin sustained release form of the invention.

Folkers et al. does not teach nor suggest any sustained release HMG-CoA reductase inhibitor formulation.

Therefore we consider Folkers et al. as not relevant because the field of invention is totally different from the present application.

Furthermore, Royce et al. is directed to a direct compression process for a preparing a tableted dosage form comprising a direct compression vehicle consisting essentially of polyethylene oxide.

Claim 1 of Royce et al. can be read as follows:

"A direct compression process for preparing a tablet pharmaceutical dosage form consisting of the steps of:

a) blending a powder for crystalling therapeutic medicament with a direct compression vehicle consisting essentially of polyethylene oxide, in absence of added solvent or heat, to form a composition in which the medicament is dispersed; and

b) compressing the resulting composition under sufficient pressure to form a tablet."

As disclosed on column 3 lines 34-42, the dosage form according to the invention can be either an immediate release or a sustained release dosage form.

There is no motivation for one skilled in the art to select fluvastatin from Folkers and use it according to Royce et al. compression's process because both references are directed toward totally different fields indicating that there is no relation between them.

Secondly there is no motivation for one skilled in the art to use fluvastatin as the active drug in Royce et al. because as disclosed in Royce et al. on column 4 lines 44-45 "The active drug that can be delivered include organic and inorganic drugs, without limitation".

Even assuming, *arguendo*, that both document were combined, this would still not lead to the composition according to the present invention because Royce et al. relates to a direct compression process in "absence of added solvent or heat" which is a different process than the one use for the manufacture of the compositions according to the present invention. Pages 14 to 16 of the specification of the present invention disclose four examples of manufacturing the pharmaceutical compositions according to the present invention. All these processes mention the use of ethanol which is a solvent and the use of heat to dry the granulation. Moreover, Examples 5.1, 5.2 and 5.4 specifically mention that the granulation is a wet granulation. Said granulation process is not compatible with a direct compression process.

The rejection of claims 1-4 and 15 under 35 U.S.C. §103(a) over Royce in view of Folkers et al. has clearly been traversed and should be withdrawn.

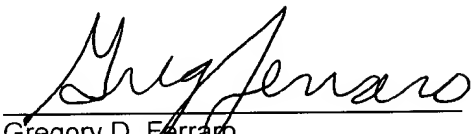
Rejection of claims 1-4 and 15 under 35 U.S.C. §112, second paragraph

Applicants respectfully traverse the rejection of claims 1-4 and 15 under 35 U.S.C. §112, second paragraph insofar as this rejection applies to the claims as amended. The Examiner stated that there was confusion concerning the location of the drug and whether the matrix contained the active ingredient. Claim 1 has been amended in order to better define the essential characteristics of the invention. The active ingredient is purposely not limited to being either in the matrix or not being there. As shown in the examples, the active ingredient is mixed with matrix material and may be enmeshed therein but also may be found in an inner area devoid of any matrix material. Claim 1 is not limiting in this regard, and is meant to encompass all formulations of active ingredient, either alone in an inner area, enmeshed with the matrix material or both. Applicants take the position that all these formulations are novel and therefore patentable and claim this aspect of the invention accordingly. Claims 1-4 and 15 are now

thought to be definite enough to satisfy the statute and, therefore, the rejection under 35 USC 112 has been traversed and should be withdrawn.

In view of the foregoing, Applicant submits the Application is now in condition for allowance and respectfully requests early notice to that effect.

Respectfully submitted,



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Date: August 20, 2003